DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Minimally Invasive Devices, LLC
% MM & A Consulting, LLC
Mark L. Friedman, Ph.D.
6329 SW 81st Road
Lake Butler, FL 32054

JUL 27 2015

Re: K102452
Trade/Device Name: Minimally Invasive Devices Defogging and Cleaning Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT
Dated (Date on orig SE ltr): December 16, 2010
Received (Date on orig SE ltr): December 20, 2010

Dear Dr. Friedman,

This letter corrects our substantially equivalent letter of December 23, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEC 2 3 2010

Indications for Use

510(k) Number (if known): K102452

Device Name: Minimally Invasive Devices Defogging and Cleaning Solution

Indications for Use:

The Defogging and Cleaning Solution is a single-use laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the laparoscope lens thereby maintaining visualization of the surgical site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102452

510(k) Summary

K102452 DEC 2 3 2010

Applicant Name and Address	Minimally Invasive Devices, Inc. 1275 Kinnear Road Columbus, Ohio 43212
Contact Person:	Caroline Crisafulli
Date of Summary:	December 16, 2010
Name of Device: Trade/Proprietary Name:	Flo-X
Common Name:	Defogging and Cleaning Solution
Establishment Name:	Minimally Invasive Devices, Inc. 1275 Kinnear Road Columbus, Ohio 43212
Establishment Number:	3007362639
Proposed Classification:	KOG Class II 21 CFR Part 876.1500, Endoscope and/or Accessories.
Panel:	General and Plastic Surgery

Predicate Devices:

K944249	Covidien Auto-Suture Anti-Fog Solution (Dexide FRED)
K982465	DeRoyal Industries, Inc. DeFogger
K080613	Minimally Invasive Devices, Inc. FloShield™ System

Intended Use:
The Defogging and Cleaning Solution is a single-use laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the laparoscope lens thereby maintaining visualization of the surgical site.

Device Description:
The Minimally Invasive Devices Defogging and Cleaning Solution is a biocompatible surfactant (Docusate Sodium) when used as indicated. It functions in the same manner as the predicate devices. It is intended to be used to prevent fogging of the lens of devices (laparoscope) that provide visualization during minimally invasive surgeries. Additionally, the solution can be used to clean the end of the lens of devices (laparoscope) that provide visualization during minimally invasive surgeries (i.e. to rinse lens intra-operatively by rinsing any debris from the lens which becomes attached to the lens as a result of the procedure.)"

Summary of Technological Characteristics:
The Defogging and Cleaning Solution is comprised of a surfactant that provides the same physical characteristics as the listed predicate devices. The Defogging and Cleaning Solution is a clear/colorless, water soluble solution that is packaged in a syringe or bottle for easy use. The

1/2

product is irradiated to ensure sterility. The defogging (anti-fogging) action of the Minimally Invasive Devices Defogging and Cleaning Solution works as a defogger in the same fashion of the predicate devices. Typically anti-fog treatments work by minimizing surface tension, resulting in a non-scattering film of water instead of single droplets, an effect called wetting. Surfactants are one compound that are used in the predicate devices to "wet" the surface of the lens

Summary of Performance Testing:
Animal and bench studies (in simulated peritoneal cavity environments) have shown that the Minimally Invasive Devices Defogging and Cleaning Solution effectively washes debris and any oil, including lipid-based debris from the lens that saline or water will are unable to wash away. The cleaning action is a simple flush across the lens (no mechanical mechanism such as wiping is needed) when needed, the surfactant properties effectively rinse/wash the debris from the lens. The surfactant will then easily flow off the lens resulting in a refreshed and clear view of the operative site without interrupting the procedure. The testing performed included the following:

Test Title	Summarized Results
Syringe Extractable Study	Testing in compliance with ISO 10993-18 was performed to demonstrate that the container did not have any extractable compound that would leach into the Defogging and Cleaning solution.
Evaluation of acute systemic toxicity of the Defogging and Cleaning Solution following a single intra-peritoneal injection into mice.	There was no mortality or evidence of systemic toxicity from the test article injected into mice.
Verification that the Minimally Invasive Devices Defogging and Cleaning Solution is effective in defogging a laparoscope lens.	This testing demonstrated that the Defogging and Cleaning Solution was effective as a defogging agent when the solution was applied to the laparoscope lens with no mechanical action such as blotting or use of a saturated sponge
Ability to Defog the Laparoscope Lens: Comparison between the Minimally Invasive Devices Defogging and Cleaning Solution and a Predicate Device	The Defogging and Cleaning Solution and the predicate device both demonstrated that they were effective and equivalent in defogging the laparoscope lens.
Ability to Clean the Laparoscope Lens: Comparison between the Minimally Invasive Devices Defogging and Cleaning Solution, Water and Saline	The results demonstrate that the Defogging and Cleaning Solution effectively removed the grease from the laparoscope lens when applied with flushing via the FloShield™ Plus System. In comparison with water and saline, the water was the least effective at cleaning the lens, saline was slightly better, but the Defogging and Cleaning Solution was superior to water and saline in clearing grease from the lens.
Effects of Irradiation on the Defogging and Cleaning Solution	Analysis of the Defogging and Cleaning Solution pre and post E-Beam irradiation to 25-40 kiloGray (kGy) demonstrates that the solution is not affected by irradiation. The Docusate component is stable and the solution properties are unchanged. pH, concentration and analysis by HPLC were used to make the assessments.
Animal Testing of the Defogging and Cleaning Solution (Porcine Peritoneal Cavity)	The Defogging and Cleaning Solution was effective in keeping the laparoscope lens defogged when applied externally and was found to be equivalent to the predicate devices in keeping the laparoscope lens defogged when applied externally. The Minimally Invasive Device Defogging and Cleaning Solution did not interfere with the function of the FloShield™ Plus System, worked in conjunction with the FloShield™ Plus System and was effective in removing/cleaning debris/blood/fat from the lens in situ when applied in 1-2 cc aliquots through the FloShield™ Plus System.

Conclusion:
The Minimally Invasive Devices Defogging and Cleaning Solution (Flo-X) is equivalent to the predicate devices in its ability to defog and keep a laparoscope lens defog during minimally invasive surgery and additionally aids in cleaning the laparoscope lens of debris that might otherwise accumulate on the lens during the course of the surgery. The Defogging and Cleaning Solution is at least as safe and effective as predicate devices.

2/2